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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,436	12/07/2000	Sudhirdas K. Prayaga	15966-615 (CURA-115)	9940

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EXAMINER
CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	17

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/732,436	PRAYAGA ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant is advised that claims 1-11 are each improper Markush claims because the elements recited therein are either three proteins or three nucleic acids which do not serve a common function which is based upon a common property or special technical feature not found in the prior art. Each of these proteins and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art proteins or nucleic acids. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a polypeptide of SEQ ID NO:2, classified in class 530, subclass 350, for example.

II. Claims 1-4, drawn to a polypeptide of SEQ ID NO:4, classified in class 530, subclass 350, for example.

III. Claims 1-4, drawn to a polypeptide of SEQ ID NO:6, classified in class 530, subclass 350, for example.

IV. Claims 5-14, drawn to nucleic acid molecule of SEQ ID NO:1, vectors and host cells, classified in class 435, subclass 69.1, for example.

V. Claims 5-14, drawn to nucleic acid molecule of SEQ ID NO:3, vectors and host cells, classified in class 435, subclass 69.1, for example.

VI. Claims 5-14, drawn to nucleic acid molecule of SEQ ID NO:5, vectors and host cells, classified in class 435, subclass 69.1, for example.

VII. Claims 15-17, drawn to antibodies to a polypeptide of SEQ ID NO:2, classified in class 530, subclass 387.1, for example.

IIX. Claims 15-17, drawn to antibodies to a polypeptide of SEQ ID NO:4, classified in class 530, subclass 387.1, for example.

IX. Claims 15-17, drawn to antibodies to a polypeptide of SEQ ID NO:6, classified in class 530, subclass 387.1, for example.

X. Claim 18, drawn to a method for determining the presence of a polypeptide of SEQ ID NO:2, classified in class 436, subclass 501, for example.

XI. Claim 18, drawn to a method for determining the presence of a polypeptide of SEQ ID NO:4, classified in class 436, subclass 501, for example.

XII. Claim 18, drawn to a method for determining the presence of a polypeptide of SEQ ID NO:6, classified in class 436, subclass 501, for example.

XIII. Claim 19, drawn to a method for determining the presence of nucleic acid of SEQ ID NO:1, classified in class 435, subclass 6, for example.

XIV. Claim 19, drawn to a method for determining the presence of nucleic acid of SEQ ID NO:3, classified in class 435, subclass 6, for example.

XV. Claim 19, drawn to a method for determining the presence of nucleic acid of SEQ ID NO:5, classified in class 435, subclass 6, for example.

XVI. Claim 20, drawn to a method of identifying a polypeptide of SEQ ID NO:2, classified in class 436, subclass 501, for example.

XVII. Claim 20, drawn to a method of identifying a polypeptide of SEQ ID NO:4, classified in class 436, subclass 501, for example.

XIIX. Claim 20, drawn to a method of identifying a polypeptide of SEQ ID NO:6, classified in class 436, subclass 501, for example.

XIX. Claim 21, drawn to a method for identifying an agent that modulates the activity of polypeptide of SEQ ID NO:2, classified in class undetermined, subclass undetermined, for example.

XX. Claim 21, drawn to a method for identifying an agent that modulates the activity of polypeptide of SEQ ID NO:4, classified in class undetermined, subclass undetermined, for example.

XXI. Claim 21, drawn to a method for identifying an agent that modulates the activity of polypeptide of SEQ ID NO:6, classified in class undetermined, subclass undetermined, for example.

XXII. Claim 22, drawn to a method for modulating the activity of polypeptide of SEQ ID NO:2, classified in class undetermined, subclass undetermined, for example.

XXIII. Claim 22, drawn to a method for modulating the activity of polypeptide of SEQ ID NO:4, classified in class undetermined, subclass undetermined, for example.

XXIV. Claim 22, drawn to a method for modulating the activity of polypeptide of SEQ ID NO:6, classified in class undetermined, subclass undetermined, for example.

XXV. Claims 23-24 and 35 drawn to a method of treating NOV-associated disorder by administration of polypeptide of SEQ ID NO:2, classified in class 514, subclass 2, for example.

XXVI. Claims 23-24 and 35 drawn to a method of treating NOV-associated disorder by administration of polypeptide of SEQ ID NO:4, classified in class 514, subclass 2, for example.

XXVII. Claims 23-24 and 35 drawn to a method of treating NOV-associated disorder by administration of polypeptide of SEQ ID NO:6, classified in class 514, subclass 2, for example.

XXIIX. Claims 25-26 and 35 drawn to a method of treating a NOV-associated disorder by administering a nucleic acid of SEQ ID NO:1, classified in class 514, subclass 44, for example.

XXIX. Claims 25-26 and 35 drawn to a method of treating a NOV-associated disorder by administering a nucleic acid of SEQ ID NO:3, classified in class 514, subclass 44, for example.

XXX. Claims 25-26 and 35 drawn to a method of treating a NOV-associated disorder by administering a nucleic acid of SEQ ID NO:5, classified in class 514, subclass 44, for example.

XXXI. Claims 27-28 and 35 drawn to a method of treatment of NOV-associated disorder by administering an antibody to a polypeptide of SEQ ID NO:2, classified in class 424, subclass 130.1, for example. Applicant is advised that claim 28 is interpreted as being dependent from claim 27.

XXXII. Claims 27-28, drawn to a method of treatment of NOV-associated disorder by administering an antibody to a polypeptide of SEQ ID NO:4, classified in class

424, subclass 130.1, for example. Applicant is advised that claim 28 is interpreted as being dependent from claim 27.

XXXIII. Claims 27-28 and 35 drawn to a method of treatment of NOV-associated disorder by administering an antibody to a polypeptide of SEQ ID NO:6, classified in class 424, subclass 130.1, for example. Applicant is advised that claim 28 is interpreted as being dependent from claim 27.

XXXIV. Claims 29 and 32, drawn to a pharmaceutical composition comprising a polypeptide of SEQ ID NO:2, classified in class 530, subclass 350, for example.

XXXV. Claims 29 and 32, drawn to a pharmaceutical composition comprising a polypeptide of SEQ ID NO:4, classified in class 530, subclass 350, for example.

XXXVI. Claims 29 and 32, drawn to a pharmaceutical composition comprising a polypeptide of SEQ ID NO:6, classified in class 530, subclass 350, for example.

XXXVII. Claims 30 and 33, drawn to a pharmaceutical composition comprising a nucleic acid of SEQ ID NO:1, classified in class 536, subclass 23.1, for example.

XXXIIX. Claims 30 and 33, drawn to a pharmaceutical composition comprising a nucleic acid of SEQ ID NO:3, classified in class 536, subclass 23.1, for example.

XXXIX. Claims 30 and 33, drawn to a pharmaceutical composition comprising a nucleic acid of SEQ ID NO:5, classified in class 536, subclass 23.1, for example.

XL. Claims 31 and 34, drawn to a pharmaceutical composition comprising an antibody to a polypeptide of SEQ ID NO:2, classified in class 530, subclass 387.1, for example.

XLI. Claims 31 and 34, drawn to a pharmaceutical composition comprising an antibody to a polypeptide of SEQ ID NO:4, classified in class 530, subclass 387.1, for example.

XLII. Claims 31 and 34, drawn to a pharmaceutical composition comprising an antibody to a polypeptide of SEQ ID NO:6, classified in class 530, subclass 387.1, for example.

XLIII. Claims 36-37, drawn to a method for screening for a predisposition to a NOV-associated disorder by measuring the activity of polypeptide of SEQ ID NO:2, classified in class undetermined, subclass undetermined, for example.

XLIV. Claims 36-37, drawn to a method for screening for a predisposition to a NOV-associated disorder by measuring the activity of polypeptide of SEQ ID NO:4, classified in class undetermined, subclass undetermined, for example.

XLV. Claims 36-37, drawn to a method for screening for a predisposition to a NOV-associated disorder by measuring the activity of polypeptide of SEQ ID NO:6, classified in class undetermined, subclass undetermined, for example.

XLVI. Claim 38, drawn to a method for determining the predisposition to a diseases associated with altered levels of polypeptide of SEQ ID NO:2, classified in class 436, subclass 501, for example.

XLVII. Claim 38, drawn to a method for determining the predisposition to a diseases associated with altered levels of polypeptide of SEQ ID NO:4, classified in class 436, subclass 501, for example.

XLIIX. Claim 38, drawn to a method for determining the predisposition to a diseases associated with altered levels of polypeptide of SEQ ID NO:6, classified in class 436, subclass 501, for example.

XLIX. Claim 39, drawn to a method for determining the predisposition to a diseases associated with altered levels of nucleic acid of SEQ ID NO:1, classified in class 536, subclass 24.3, for example.

L. Claim 39, drawn to a method for determining the predisposition to a diseases associated with altered levels of nucleic acid of SEQ ID NO:3, classified in class 536, subclass 24.3, for example.

LI. Claim 39, drawn to a method for determining the predisposition to a diseases associated with altered levels of nucleic acid of SEQ ID NO:5, classified in class 536, subclass 24.3, for example.

LII. Claim 40, drawn to a method of treating a pathological state in a mammal by administering a polypeptide of SEQ IF NO:2, classified in class 524, subclass 2, for example.

LIII. Claim 40, drawn to a method of treating a pathological state in a mammal by administering a polypeptide of SEQ IF NO:4, classified in class 524, subclass 2, for example.

LIV. Claim 40, drawn to a method of treating a pathological state in a mammal by administering a polypeptide of SEQ IF NO:6, classified in class 524, subclass 2, for example.

LV. Claim 41, drawn to a method of treating a pathological state in a mammal by administering an antibody to a polypeptide of SEQ IF NO:2, classified in class 424, subclass 130.1, for example.

LVI. Claim 41, drawn to a method of treating a pathological state in a mammal by administering an antibody to a polypeptide of SEQ IF NO:4, classified in class 424, subclass 130.1, for example.

LVII. Claim 41, drawn to a method of treating a pathological state in a mammal by administering an antibody to a polypeptide of SEQ IF NO:6, classified in class 424, subclass 130.1, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions (I, IV, VII, X, XIII, XVI, XIX, XXII, XXV, XXIIX, XXXI, XXXIV, XXXVII, XL, XLIII, XLVI, XLIX, LII, LV), (II, V, IIX, XI, XIV, XVII, XX, XXIII, XVI, XXIX, XXXII, XXXV, XXXIIX, XLI, XLIV, XLVII, L, LIII, LVI) and (III, VI, IX, XII, XV, XIIX, XXI, XXIV, XXVII, XXX, XXXIII, XXXVI, XXXIX, XLII, XLV, XLIIX, LI, LIV, LVII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the inventions directed to nucleic acid of SEQ ID NO: 1, encoding polypeptide of SEQ ID NO:2, nucleic acid of SEQ ID NO:3, encoding polypeptide of SEQ ID NO:4 and nucleic acid of SEQ ID NO:5 encoding polypeptide of SEQ ID NO:6 can be used independently as they represent different molecular embodiments serving different functions, therefore constituting patentably distinct entities.

3. Inventions (I-III) and IV-VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Groups (IV-VI) and polypeptides of Groups (I-III) are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization assay.

4. Inventions (IV-VI) and (VII-IX) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, antibodies of Groups (VII-IX) can also be used in materially different methods, such as in various diagnostic (e.g. as a probe in immunoassays or immunochromatography), or therapeutic methods.

5. Inventions (I-III) and (VII-IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the polypeptides of Groups (I-III) and antibodies of Groups (VII-IX) are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and entirely different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein.

6. Inventions (I-III) and (XXXIV-XLII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups (I-III) could be used in an entirely different manner such as for the production of antibodies rather than in the pharmaceutical compositions of Groups (XXXIV-XLII).

7. Inventions X-XXXIII, XLIII-LVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
March 21, 2002 OC

JOHN ULM
PRIMARY EXAMINER
GROUP 1800